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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,900	12/22/2005	Jorge Hernan Jimenez	GTRC135	3089

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
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3774

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/561,900	Applicant(s) JIMENEZ ET AL.	
	Examiner William H. Matthews (Howie)	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 39-50 have been considered but are moot in view of the new ground(s) of rejection. Applicants arguments with respect to differences of the claimed invention and prior art are addressed below. (directly coupled ends, three-dimensionally deformable, forming a full continuous ring, being saddle shaped). Furthermore, Applicant argues against the combination with, or teachings taken from Wright because Wright does not enable how to modify each of the cited primary references (Quijano, Marquez, Carpentier). Examiner respectfully disagrees. Modeling a device to be or provide a saddle-shaped annulus would be readily apparent to one of ordinary skill in the art. For example, with respect to Carpentier, segment 18 would merely require an upward curve or bulge or changed to more flexible material which would provide for saddle shapes.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 39 recites “ends directly, flexibly coupled to each other” which is not recited in the specification so as to ascertain the meaning of directly, flexibly coupled. Examiner interpret directly coupled to encompass a device where no other structure couples the ends (e.g. a pin or weld as used in Applicant’s chains 22 and 12). The chain embodiment 42 (scaled chain) is not clearly described in the specification or drawings and examiner is unable to determine if links with ends are present, and if so whether they are directly coupled. Nevertheless, chain 42 does not provide a “constant diameter” (claim 1, line 4) since paragraph 0053 describes a 2% variation. A similar issue exists with **claims 45-46, and 49**.

Claims 39,45,46,49 recite “moldable” which is not disclosed and encompasses a material which is malleable like soft clay. The claims already recite the rings as deformable so the intent of “moldable” is unclear.

Claims 44-45,50 each recite new language that is not supported in the specification at paragraphs 0113-0119 as proposed by Applicant, particularly a reduction of force on an intermediate chord is not described.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 40-42,46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 40,42 recite the ring as approximately constant which broadens the scope of independent claim 39. Thus the claims are unclear whether the ring has a constant or approximately constant perimeter. Similarly, **claim 46** recites both types of perimeters.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 39-50 are rejected under 35 U.S.C. 102(e) as being anticipated by, or in the alternative under 35 U.S.C. 103(a) as being unpatentable over Quijano et al. US PUB 20030050693.

Quijano disclose in figures 1-7 an annuloplasty device comprising a chain of a plurality of links configured for implantation without necessity of suture stabilizers or placement bands and configured to provide a constant three dimensional perimeter. The device may comprise a full continuous ring (para 0042) whereby the links are flexibly coupled to adjacent links.

Note the functional aspects of the claimed device are recited upon an intended use situation, whereby the resulting effects are dependent upon the manner in which the device is implanted. The Quijano device is fully capable of use as claimed to provide chordal force changes and various shapes to the annulus, as best understood, as well as providing a substantially fixed perimeter. Furthermore, "three-dimensionally deformable" would encompass structures which can be bent in all directions such as a paper clip or the metallic ring in Quijano. A "previous state" is unclear as to what said previous state was, and may be interpreted broadly. The state may be considered a non-regurgitating state which is the goal in Quijano. See MPEP 2114.

Regarding claims 39 and 45, Quijano meets the claims as described above. However, if the limitations regarding reducing forces or substantially restoring a previous shape are not inherent, Examiner maintains it would have been obvious to implant the Quijano ring to perform such functions since the Quijano teach the purpose is to reshape a dilated annulus (0007) and thus the rings controllable reduce the

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diameter back to a previous size. Furthermore, by modifying an annulus, the intrinsic forces within the chords would change such that at least one would be expected to decrease in intensity.

Regarding claims 40-41,46-49, Quijano lacks the explicit disclosure of providing a saddle shaped structure having a saddle height to commissural diameter ratio of about 25% or 0-33%. However, Quijano does teach the device may comprise a variety of shapes (para 0042) with examples given in USPN 5201880 (Wright, incorporated by reference). Quijano further disclose the ring segments may include flexible materials as opposed to rigid metals (see para 5,39). Quijano further appreciates the goal of providing a ring which permits natural flexibility during the cardiac cycle (para 4). Wright '880 teach saddle shapes with approximate ratios as claimed (figure 4) and further teach the natural shape of the annulus is saddle shaped (column 3, lines 36-51). Therefore, if not inherently taught in Quijano, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the chain structure of Quijano to include a saddle shape in the ratio as claimed since Quijano teaches the device may assume various shapes including saddle shapes and it would be readily obvious to shape the device to follow the natural shape of the mitral valve annulus. Such a configuration is achievable through the use of flexible materials as taught in Quijano or by altering or substituting the linkage means to a well known mechanical linkage that allows for three dimensional movement (ball and socket as in Carpentier '698 below, a wire or tether, hoops (as in a bracelet or keychain), etc).

Claims 39-50 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Carpentier et al. USPN 4917698 in view of Wright USPN 5201880.

Carpentier disclose in Figures 1-2 an annuloplasty band prosthesis comprising a chain of a plurality of links (24,26). The prosthesis maintains an approximate constant perimeter which would follow radially inward and outward at points 36,38. The link end connections are considered to meet the claimed phrase “ends directly, flexibly coupled to each other” because there is no other structure between the concave/convex ends. Furthermore, the claims do not exclude another ring component which assists in forming the complete continuous ring.

With respect to claims claims 40-41 and 46-50, connections 36,38 appear to inherently allow the device to assume a saddle-shape geometry capable of deformation three-dimensionally while maintaining an approximately constant perimeter, as claimed. Note “saddle-shaped” does not require a specific shape but rather a relatively close shape (i.e. circular shaped may include an ellipse or a circle including a straight edge along the perimeter). Alternatively, if not inherent, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the prosthesis of Carpentier to assume, or allow for a variety of saddle shape ratios as taught in Wright ‘880 at column 3 lines 36-51 in order to accommodate the natural shape of a variety of mitral valve annuluses.

Note the functional aspects of the claimed device are recited upon an intended use situation, whereby the resulting effects are dependent upon the manner in which

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the device is implanted. The Carpentier device appears fully capable of use as claimed to provide changes in chordal force and various shapes to the annulus, as best understood, as well as providing a substantially fixed perimeter. The ratio of height to diameter would be fully capable upon selection of a flexible connection at 36,38. See MPEP 2114.

Claims 39-50 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Marquez USPN 2003/0040793 in view of Wright USPN 5201880.

Marquez disclose in Figures 4a-4b an annuloplasty band prosthesis comprising a chain 60 of a plurality of connected links 70. The prosthesis is described to maintain a desired perimeter due to the contracting force of inner member 72, said member directly and/or flexibly connecting ends of links 70. A complete continuous ring is shown in each of Figures 4A and 4B, whereby in figure 4B the perimeter would include the outer surface of connectors 72.

With respect to claims 39,40,42,43, and 46, Marquez teach the benefits of rigid rings providing a fixed diameter (background). The device of Figures 4a-4b is described to provide flexibility to assist implantation of the ring to dilated valves, and a contractile force to provide a pre-determined diameter. The contractile force may be provided from a variety of elastic materials. If not inherent that the implanted device would provide an essentially constant diameter (perimeter), it would have been obvious to one of ordinary skill in the art at the time of the invention to select to sufficiently contracting materials

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that overcome the expanding force of the valve during use in order to achieve the predetermined, fixed diameter taught by Marquez.

With respect to claims 40-41 and 46-50, Marquez is silent as to providing a saddle-shape geometry capable of deformation three-dimensionally while maintaining an approximately constant perimeter, and further wherein the saddle shape comprising a ratio of height to diameter of approximately 0-33% or 25%. Wright teaches at column 3 lines 36-51 that mitral valves have a saddle shaped annulus and further teach rings having saddle shape features to conform to the annulus. Note Marquez does teach a desire to provide a ring conforming to the shape of the mitral valve annulus (para 29). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the prosthesis of Marquez to assume a saddle shape as taught in Wright '880 in order to properly conform to the natural shape of a mitral valve annulus. Furthermore, providing the saddle shape in the ratios as claimed would be readily apparent to one of ordinary skill in the art in order to accommodate a wide variation of mitral valve annulus shapes and sizes of a population of patients.

Note the functional aspects of the claimed device are recited upon an intended use situation, whereby the resulting effects are dependent upon the manner in which the device is implanted. The Marquez device appears fully capable of use as claimed to provide reduced chordal force and various shapes to the annulus, as best understood, as well as providing a substantially fixed perimeter. See MPEP 2114.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 571-272-4753. The examiner can normally be reached on Monday-Friday 10-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David J. Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Matthews/
Primary Examiner
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